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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,632	11/25/1997	ELAZAR RABBANI	ENZ-53(C)	4638

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EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/978,632

Applicant(s)

RABBANI ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 246-270 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 246-270 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112/Response to Arguments

2. Claims 246-270 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons of record as set forth in the Official action mailed 02/03/99, 11/08/99 and 12/19/00 for old claims 1-24 and 245, and as set forth in the Official action mailed 08/28/01 for claims 246-270.

Applicant's arguments filed 2/28/02 have been fully considered but they are not persuasive. Applicants' reply is found on pages 5-10 of the response.

Applicant cites on pages 5, 6, and 7, certain passages from the guidelines to explain the standards for teaching "possession" of an invention as well as standards for "a representative number of species" of a claimed genus.

Applicants' assert that an adequate description has been provided and point to pages 33-47 and 53 of the specification to teach descriptions of the claimed constructs. Applicants' further

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point to figures 1-7 to show use of drawings to show description of the claimed invention.

Applicants' further note that actual reduction to practice is not required to satisfy the written description requirement.

In response, **MPEP 2163** teaches the following conditions for the analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and level of skill in the art at the time the invention was made:

The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence....A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process....Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement....The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The specification as filed teaches in the figures numerous potential constructs using certain modified features for production of products in a cell. Primarily, the specification teaches vector-type constructs having features which are meant to enhance the vector-like constructs for

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targeting the expressed product in a cell. Such vector-type constructs require specific sequences of nucleic acids, modified nucleotides or analogs for the expression of the claimed products: antisense RNA, antisense DNA, sense RNA, ribozymes, decoys, messenger RNA or protein.

Neither the specification nor the drawings provided a clear picture of the completed vector-type constructs contemplated, such that one of skill in the art would have been able to immediately envisage the finished product since a representative number of species of such constructs is not adequately described by the most basic necessary chemical and physical structure of nucleic acid constructs, the nucleic acid sequence structure. Most of the drawings in the instant specification taught "ball-and stick" vector-type constructs having a partial idea of the pertinent features of the vectors, but not having a substantially complete sequence. Applicant argues that a reduction to practice is not necessary at the time of the invention, but in the instant case, knowledge of the sequence would be necessary for synthesizing the actual constructs. When considering that instant claim 246 claims any vector construct made of nucleic acids that when present in a cell produces a product, the breath of the claimed invention is extremely broad. From viewing the drawings, for instance figures 1-7 as pointed out by Applicant, one of skill in the art would envision a primer with any ligand(s) attaching to what appears to stand for a nucleic acid vector and primers having fusogenic peptides and tails. The specification teaches prophetically on pages 33-47 the design of any vector construct having such ligands and additional modifications. There is no evidence on the record of a relationship between the structure of the lines and features in drawings 1-7 for instance to specific nucleic acid sequences

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of vectors or the use of known vectors from which specific modifications may be added. Sequence structure of nucleic acids is a necessary starting point for making a vector for expression of nucleic acid products as claimed. One of skill in the art would not have recognized that Applicant was in possession of a representative number of species of any finished expression vectors in view of the teachings of figures 1-7 and pages 33-47 of the specification since no specific guidance was given for the design of the most basic elements of the claimed nucleic acid constructs. The scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made and in what order. The general knowledge and level of skill in the art do not supplement the omitted description of sequence structure, as a starting point for instance, because specific, not general, guidance is what is needed for making the finished constructs. For these reasons, Applicant was not in possession of the claimed genus at the time the invention was made.

Claim Rejections - 35 USC § 102/Response to Arguments

3. New claims 246-270 stand rejected under 35 U.S.C. 102(e) as being anticipated by Meyer et al. for the same reasons of record as set forth in the Official action mailed 02/03/99, 11/08/99

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and 12/19/00 for old claims 1-24, and as set forth in the Official action mailed 08/28/01 for claims 246-270.

Applicant's arguments filed 2/28/02 have been fully considered but they are not persuasive.

Applicants' assert that Meyer et al. does not teach constructs defined by the instant specification and state that the ODN-peptide conjugates of Meyer et al. clearly are not constructs because "the conjugates cannot integrate into cellular nucleic acid or exist in an extrachromosomal state. The ODN-peptide conjugates certainly cannot propagate copies of itself in either the integrated or the extrachromosomal state. In other words, the ODN-peptide conjugates of Meyer et al. are not capable of self replication."

In response, Applicant is arguing limitations of the claimed constructs which are not present in the claims. The claims do not require that the constructs integrate into cellular nucleic acid or exist in an extrachromosomal state, nor that they can propagate copies and are capable of self replication. Claim 247 recites wherein the construct is linear. The claims don't recite that such linear constructs self-replicate.

Meyer et al. thus continues to anticipate the claimed invention.

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4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
May 16, 2002

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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